

**REMARKS/ARGUMENTS**

Claims 75, 77, 84-89 and 91 are pending. By way of the present amendment, three (3) claims have been amended. Applicant respectfully submits that no new matter has been added by way of this amendment.

Claim	Illustrative support in the specification can be found at least at:
75	Page 35:14-20; page 36:10-20; page 44:10-30; page 45:10-47:20.
77	Page 35:14-20; page 36:10-20; page 44:10-30; page 45:10-47:20.
91	Amended per the Examiner's suggestion to keep language consistent.

**I. SPECIFICATION AND PRIORITY**

The Office Action dated May 26, 2010 objected to the amendment filed June 11, 2007 as introducing new matter to the disclosure – “[t]he added material which is not supported by the original disclosure is as follows: The range of ‘about 0.75 mEq (mmole) to about [sic] [1.5] mEq (mmol) per 2 mg of omeprazole.’” See Office Action, at page 2. Applicant respectfully submits that support for the range can be found at least in U.S. patent application, no. 09/183,422 on page 23, lines 10-13. This portion of the application states that the amount of sodium bicarbonate employed could include “a range of approximately 0.75 meq (mmole) to 1.5 meq (mmole) per 2 mg of omeprazole.”

Since the instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346, which is a continuation-in-part of application, no. 09/183,422, filed on October 30, 1998, Applicant respectfully submits that the amendments filed by way of the present amendment or any prior amendments during prosecution of this application does not constitute new matter and requests withdrawal of the objection.

**II. THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN.**

The Office Action rejected claims 75, 77, 84-89 and 91 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicant respectfully disagrees with the Office Action's assertion that the proposed claims lack written description support. Regarding the term “a buffer in an amount more than about 20 times the amount of the omeprazole,” applicant respectfully submits that exemplary

support can be found throughout the specification. For example, the specification discloses tablets with about 250 mg of sodium bicarbonate and 10 mg of omeprazole, a ratio of about 25:1, which is more than about 20 to 1 by weight. *See, e.g.*, 45:12-17 and 47:1-7. The specification also discloses a tablet with about 500 mg of sodium bicarbonate and 20 mg of omeprazole, a ratio of about 25:1, which is more than about 20 to 1 by weight. *See, e.g.*, 46:14-19. The specification further discloses a tablet with about 400 mg of sodium bicarbonate and 10 mg of omeprazole, a ratio of about 40:1, which is more than about 20 to 1 by weight. *See, e.g.*, 47:23-28 and 48:18-23. The specification also discloses tablets with about 975 mg of sodium bicarbonate and 20 mg of omeprazole, a ratio of about 50:1, which is more than about 20 to 1 by weight. *See, e.g.*, 47:23-28 and 48:18-23.

Applicant notes the Examiner's comments regarding the word "about" in claim 91 and has made the changes suggested to keep language consistent.

Therefore, in view of the present amendments and foregoing remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, and should be withdrawn.

### **III. THE REJECTION UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN.**

The Office Action rejected claims 75, 77, 84-89 and 91 under 102(b) based on U.S. Patent No. 6,489,346 ("Phillips"). As discussed in Section I, above, no new matter has been added to the present specification, and support can be found throughout the priority documents. In addition, the portions of U.S. Patent No. 6,489,346 cited by the Office Action overlap with those portions of the present application cited for support for the present claims. Therefore, there is no new matter introduced by way of this or any previously filed preliminary amendments. Accordingly, U.S. Patent No. 6,489,346 is not available as a 102(b) reference, since the instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346. Applicant respectfully requests that the rejection under 102(b) be withdrawn in light of the current amendments and remarks.

**IV. THE REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN.**

Claims 75, 77, 84-89 and 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,447,918 ("McCullough") in view of Carroll, EP 584,588 ("Nomura") or US 6,268,385 ("Whittle").<sup>1</sup> Applicant respectfully traverses this rejection, since no combination of the references cited disclose every feature of the pending amended claims. Further, there is no apparent reason to combine the references in the manner suggest by the examiner nor a reasonable expectation of success thereof.

The references cited in the Office Action dated May 26, 2010, alone or in combination, fail to teach all limitations of the claims as presently amended. McCullough's teachings focus on compositions requiring the use of sucralfate. By contrast, the present invention improves upon embodiments using sucralfate as the active ingredient. *See, e.g.*, 8:3-18, 15:19-22, 22:27-31, 51:5-10. In fact, although McCullough attempts to make various combinations with various acid-related active ingredients, the cited portions of McCullough (Columns 15-16, example 12) never teach the use of a tablet comprising non-enteric coated omeprazole and sodium bicarbonate in the ranges claimed together with a disintegrant.

Similarly, Carroll and Whittle fail to render the pending claims obvious. Carroll fails to teach a tablet formulation of non-enteric coated omeprazole, and Whittle does not teach the use of a non-enteric coated proton pump inhibitor in a tablet dosage form, let alone non-enteric coated omeprazole with sodium bicarbonate in the claimed ranges.

As discussed previously, Nomura teaches that the total basic material to anti-ulcer compound weight ratio must be less than 20:1. *See* Nomura at 6:17-21. Applicant does not see where Nomura discloses the claimed amounts of sodium bicarbonate and non-enteric coated omeprazole in a tablet. Rather, Nomura teaches away from such larger quantities of buffer.

Based on the foregoing reasons and amendments, a *prima facie* case of obviousness has not been established. Accordingly, amended claims 75, 77, 84-89 and 91 are not obvious over the cited references. Therefore, Applicant respectfully requests withdrawal of this rejection.

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<sup>1</sup> Applicant respectfully submits that the rejections made in any office actions in the present application are interpreted as being limited to those references specifically identified in each office action. Applicant reserves the right to further traverse, amend, supplement or otherwise respond to rejections to the extent they are based on references not expressly named. Furthermore, Applicant reserves the right to claim a priority date at least as early as January 4, 1996.

**V. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING**

Claims 75, 77, 84-89 and 91 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over various claims of co-pending Application Nos. 10/407,522 and 10/418,410. In addition, Claims 75, 77, 84-89 and 91 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over several claims of U.S. Patent Nos. 6,780,882, 6,699,885 and 7,399,772. Applicant will submit a terminal disclaimer once allowable subject matter is indicated.

**CONCLUSION**

For at least the foregoing reasons, it is respectfully submitted that the claims as submitted by way of this amendment are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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